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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,281	08/01/2003	William Leon Elliott	PC20553A	5098
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WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105				
EXAMINER DELACROIX MUIRHEI, CYBILLE				
ART UNIT		PAPER NUMBER		
1614				

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,281

Applicant(s)

ELLIOTT ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

The following is responsive to the preliminary amendment received Aug. 1, 2003.

Claims 1-15 are presented for prosecution on the merits.

Information Disclosure Statement(s)

Applicant's Information Disclosure Statement received Dec. 29, 2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Objection(s)

1. Claims 5, 8, 14-15 are objected to because of the following informalities: in claim 5, line 2, "comprising" should be deleted and replaced with --consisting of--. In claim 8, line 1, "combination" should be cancelled and replaced with --method--. In claims 14, 15, line 2, --erbB-- should be added before "tyrosine kinase inhibitor." Appropriate correction is required.

Claim Rejection(s)—35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 6-9, 10, 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "said cancer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 11-12 recite the limitation "CI-1033" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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Claim 12 recites the limitation "taxotere" in line 3. There is insufficient antecedent basis for this limitation in the claim.

In claims 1 and 9, the limitations "cell proliferative diseases" and "hyper-proliferative cellular disorder" render the claims vague and indefinite. The specification does not clearly set forth explicitly and with reasonable clarity the definition of these limitations. Instead, what is described at page 10, lines 21-22 appears to be merely exemplary and does not describe what would be excluded by the limitations. Therefore, the metes and bounds of the patent protection desired are unclear, and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed method.

Claim Rejection(s)—35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5-8, 9-10, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9931140.

WO '140 discloses a method for treating cancer disorders over-expressing ErbB2, the method comprising administering to a patient in need thereof an effective amount of an anti-ErbB2 antibody in combination with a chemotherapeutic agent such

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as gemcitabine. The chemotherapeutic agent is preferably is a taxoid such as paclitaxel. The cancers that can be treated are lung cancer, pancreatic cancer, bladder cancer, etc. Finally, WO '140 teaches that the two agents can be administered at the same time or consecutively, in either order. Please see the abstract; page 3, page 10, lines 10-35; page 11; page 25, lines 34-38.

4. Claims 1-3, 5, 9-10 rejected under 35 U.S.C. 102(a) as being anticipated by WO 0241828 ('828).

WO '828 discloses a method of treating cellular proliferative disorders such as cancer (prostate, breast, pancreatic, colon, etc.), the method comprising administering to a patient in need thereof an effective amount of an erbB-2 inhibitor selected from the group consisting of soluble extract of houttuyninum, or compound houttuyninum, Houttuynia cordata, neo-houttuyninum or analogs thereof. WO '828 also discloses that the erbB-2 inhibitors may be administered in combination with another anti-cancer compound (cisplatin) or radiation. WO '828 also discloses that the methods also include the treatment of psoriasis. Please see the abstract; page 13, line 1; claims 1-15.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4, 5, 11, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al.

Rao et al. disclose a method of treating ErbB-over expressing human breast cancer cells with a combination of ionizing radiation and the ErbB inhibitor, CI-1033. Rao et al. disclose that the combination has synergistic effects against the breast cancer cells. Please see the abstract.

Rao et al. do not specifically disclose an in vivo therapeutic method of treating cancer, i.e. breast cancer, in a patient in need thereof; however, it would have been

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obvious to one of ordinary skill in the art at the time the invention was made to administer the combination to a patient suffering from breast cancer because, based on the desirable synergistic effects disclosed by Rao et al., one of ordinary skill in the art would reasonably expect the synergistic effects of the combination of CI-1033 and ionizing radiation to effectively treat a patient suffering from breast cancer.

Conclusion

Claims 1-15 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CDM

Oct. 1, 2004


Cybille Delacroix-Muirheid
Patent Examiner Group 1600